



CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE
BOARD OF PHARMACY

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: DPR.DELAWARE.GOV
EMAIL: customerservice.dpr@state.de.us

PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, November 18, 2015 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	January 20, 2016

MEMBERS PRESENT

Susan Esposito, R.Ph., Professional Member, President
Hooshang Shanehsaz, R.Ph., Professional Member, Vice President
Kimberly Robbins, R.Ph., Professional Member
Tejal Patel, PharmD, Professional Member
Bonnie Wallner, R.Ph., Professional Member
Joli Martini, R.Ph., Professional Member
Kenneth Sellers, Public Member
Julia Wheatley, Public Member
Jay Galloway, Public Member

MEMBERS ABSENT

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

David Dryden, Executive Secretary
Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Amy Bixler
Eric Brauch
Justin Cregg
Phil Anderson
Cherryl Heiks
Jaime Frink
Jeffrey Clinton Hopkins
Casey Marvel
Kevin Morgan
Suzanne Raab-Long
Ken Harrington
Stephanie Kuratnick
Brian Adelsberger
Nancy Sawyer
Stephanie Perillo
Shauna Vogl
Amanda Valentin

Edward Suh
Dot Haut
Frank Agyei-Yeboah
Tiffany Sorey

CALL TO ORDER

Ms. Esposito called the meeting to order at 9:33 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Shanehsaz and seconded by Ms. Martini, to approve the meeting minutes for October 21, 2015 with corrections. The motion unanimously carried.

PRESIDENT'S REPORT

Ms. Esposito stated that she attended the Pennsylvania Society of Pharmacists. The society is making a push for Provider status in that state. She also attended the FDA meeting in Washington DC. The topics of discussion included 797 updates, USP800-Supply Chain Act, and more clearly defining 503A patient specific vs. 503B Out of State Facilities differences. Discussion more specifically included possible requirements to go through a 3rd party inspector for licensure approval because FDA inspections are more GMP focused rather than USP797 focused. Many states are utilizing the inspection availability that the National Boards of Pharmacy has available to resolve this issue. Clearly defining what a unit is was also mentioned due to current confusion. Much discussion regarding the differences of 503A to 503B related to the need of a 503A becoming a 503B facility based on the 30% product manufactured ruling. Ms. Esposito also stated that USP800 Supply Chain Act brings other issues to be considered. Review of current Delaware regulations should occur to ensure that Delaware stays in line with these requirements.

UNFINISHED BUSINESS

Complaint Status

13-09-11 – Assigned to Hearing Officer
13-12-11 – Assigned to Hearing Officer
13-19-11 – Forwarded to Office of Attorney General
13-01-13 – Forwarded to Office of Attorney General
13-04-13 – Forwarded to Office of Attorney General
13-05-13 – Forwarded to Office of Attorney General
13-06-13 – Forwarded to Office of Attorney General
13-20-13 – Forwarded to Office of Attorney General
13-26-13 – Assigned to Hearing Officer
13-01-14 – Forwarded to Office of Attorney General
13-03-14 – Forwarded to Office of Attorney General
13-04-14 – Forwarded to Office of Attorney General
13-06-14 – Forwarded to Office of Attorney General
13-07-14 – Forwarded to Office of Attorney General
13-09-14 – Forwarded to Office of Attorney General
13-10-14 – Forwarded to Office of Attorney General
13-11-14 – Forwarded to Office of Attorney General
13-12-14 – Forwarded to Office of Attorney General
13-13-14 – Assigned
13-14-14 – Forwarded to Office of Attorney General
13-17-14 – Assigned

Re-Review Propose to Deny Application

Empire Specialty Pharmacy – a motion to approve the application was made by Mr. Sellers and seconded by Mr. Galloway. The motion unanimously carried.

A motion to move to agenda item 5.0.1 was made by Ms. Patel and seconded by Ms. Robbins. The motion unanimously carried.

Naloxone Standing Orders

Mr. Dryden provided the members a copy of a “Patient Education Handout-How to respond in an Overdose” for review. He also provided a copy of an alert sent to Delaware licensed “Pharmacist” titled “Nasal Naloxone For Opiate Overdose” for review.

Reliant Behavioral Health – Delaware Professionals Health Monitoring Program Presentation

Christopher Hamilton, PhD, Program Director and Christa Lee, MSW, Agreement Monitor presented the board members with an update for the program since its inception. Mr. Hamilton and Ms. Lee provided statistical information for services provided as well as provided the board an opportunity to ask questions.

Deliberations on Proposed Changes to Regulation 5.1.7

Ms. Kelly brought the deliberations to order. Written comment received during the comment period was entered into the record. Exhibit #1 written comment received from Mr. David Dryden, Executive Secretary of the Board of Pharmacy was provided to the board for review. The Board read the exhibits and began deliberations. A motion to approve the proposed regulation 5.1.7 was made by Mr. Shanehsaz and seconded by Mr. Sellers. The motion unanimously carried.

Review of Tabled Application

IV Solutions – a motion to approve the application was made by Ms. Martini and seconded by Ms. Wallner. The motion unanimously carried.

Statutory and Regulatory Discussion

- Ongoing - Practitioner/Pharmacy Ownership – bill preparation in process
- Ongoing - Provision for Disciplinary Action – Ms. Kelly and Mr. Dryden to discuss further
- Ongoing - Pharmacy Technician Regulation – Proposed Regulation Approved
- Ongoing - Clarification of §2512(e)(f), Inactive Status - bill preparation in process

Re-review of Propose to Deny Application

Cystic Fibrosis Services - a motion to approve the application was made by Ms. Robbins and seconded by Ms. Martini. The motion unanimously carried.

A motion to move to agenda item 4.3.1 was made by Ms. Martini and seconded by Mr. Galloway. The motion unanimously carried.

Hearing - Propose to Deny Application

Trilogy Pharmacy - a motion to approve the application was made by Mr. Shanehsaz and seconded by Mr. Galloway. The motion unanimously carried.

NEW BUSINESS

Ms. Esposito read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:	A1-0004861	Perrone, Jeffrey Allen
	A1-0004862	Ceranski, Lena
	A1-0004863	Rowlands, Joseph
	A1-0004864	Magett, Temeka
	A1-0004865	Rada, Michael Edwin
	A1-0004866	Zayed, Alya
	A1-0004867	Schmidt, Jane Elizabeth
	A1-0004868	Bonofiglio, Ralph Michael
	A1-0004869	Becker, Christina Marie
	A1-0004870	McCool, Thomas Joseph
	A1-0004871	Shah, Nikunj N
	A1-0004872	Bot, David D.

A1-0004873 Kim, Sarah Youngeun
A1-0004874 Jozwiak, Dorota J.

A motion was made by Mr. Shanehsaz and seconded by Ms. Ms. Robbins to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern: None

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001742 Advanced Care Scripts, Inc. dba ACS Pharmacy
A9-0001743 ASCO Healthcare, LLC dba Omnicare of Annapolis Junction
A9-0001744 ASCO Healthcare, LLC dba Omnicare of Salisbury
A9-0001745 Care4, L.P. dba Omnicare of Edison
A9-0001746 Jack P. Herick Inc., dba Glades Drugs
A9-0001747 Great Lakes Medical Pharmacy, LLC
A9-0001748 G & K Pharmacy dba Glades Drugs
A9-0001749 Ethical Factor Rx LLC
A9-0001750 Gabecare Direct Rx, Inc.
A9-0001751 American Specialty Pharmacy, Inc.
A9-0001752 Vanderbilt Integrated Pharmacy
A9-0001753 Sina Drug, LLC
A9-0001754 Pharmatek Pharmacy, Inc.
A9-0001755 CSR Company, Inc.
A9-0001756 RoxSan Pharmacy, Inc.
A9-0001757 United Apothecary, Inc. dba Riddle Drugs #3
A9-0001758 Healthcare Evolution
A9-0001759 ESI Mail Order Processing, Inc. dba Express Scripts
A9-0001760 Pharmaceutic Labs, LLC
A9-0001761 Main Avenue Pharmacy, Inc.
A9-0001762 Benzer Pharmacy

A motion was made by Mr. Shanehsaz and seconded by Ms. Robbins to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0000510 The Harvard Drug Group, LLC dba Major Pharmaceuticals
A4-0002251 Trigen Laboratories, LLC
A4-0002252 BDI Pharma, Inc.
A4-0002253 Amneal Pharmaceuticals LLC
A4-0002254 YS Marketing, Inc. dba NUMED
A4-0002256 Hospira Worldwide, Inc.
A4-0002257 Hospira Worldwide, Inc.

A motion was made by Mr. Shanehsaz and seconded by Ms. Robbins to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

None

Retail Pharmacy Licensure Approval Ratification

A3-0000992 Acme Markets, Inc. dba Acme Pharmacy #2679

A motion was made by Mr. Shanehsaz and seconded by Ms. Robbins to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Retail Pharmacy Temporary Licensure Approval Ratification
None

Outsourcing Facility

AA-0000017 Cantrell Drug Company, Inc.
AA-0000018 Unique Pharmaceuticals LTD

A motion was made by Mr. Shanehsaz and seconded by Ms. Robbins to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins conducted PIC interviews with:

Casey Marvel, Walgreens Laurel, Delaware
Amanda Valentin, Walmart Rehoboth, Delaware
Frank Agyei-Yeboah, Rite Aid Millsboro, Delaware
Stephanie Kuratnick, Walgreens Newark, Delaware
Ken Harrington, Rite Aid Bear, Delaware*
Stephanie Perillo, Walgreens Middletown, Delaware*

*A motion to add these individuals for PICS interviews was made by Mr. Shanehsaz and seconded by Ms. Patel. The motion carried unanimously.

Ms. Robbins conducted the PIC interviews.

Board Review of Hearing Officer Recommendations

Cheryl Peterson, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Shanehsaz and seconded by Mr. Sellers. Ms. Esposito recused herself and the motion carried.

Mahendra Chaudhari, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Sellers and seconded by Ms. Martini. The motion unanimously carried.

Michael Spinn, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Shanehsaz and seconded by Mr. Galloway. The motion unanimously carried.

Muzit Iyassu, a motion to approve the Hearing Officer Recommendation as written was made by Ms. Wallner and seconded by Mr. Shanehsaz. The motion unanimously carried.

Board Review of Facility Applications

UPS Supply Chain Solutions N.J., a motion to approve was made by Mr. Shanehsaz and seconded by Mr. Sellers. The motion unanimously carried.

Caremark Arizona Specialty Pharmacy., a motion to approve was made by Mr. Shanehsaz and seconded by Ms. Patel. The motion unanimously carried.

Continuing Education Approval

Mr. David Dryden submitted the required continuing education approval forms for review by the board. A motion to approve the request was made by Ms. Robbins and seconded by Mr. Shanehsaz. The motion unanimously carried.

COMMITTEE REPORTS

Legislative – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and David Dryden

The committee continues to review the current crimes listing in comparison to similar healthcare professions. The next scheduled meeting will be on November 18, 2015 immediately following the Board of Pharmacy meeting.

Mr. Dryden also provided the members a copy of Senate Bill #162 – Access to Emergency Medication. The board members expressed that this bill presents concerns such as:

- Who writes the prescription?
- Who diagnoses the medical emergency?
- Has proper training been provided?
- Is there a standing order for the prescription?
- Medications not patient specific?
- Are drugs properly stored (climate, expired drugs)?
- How will the medications be distributed to the public locations?
- Board of Pharmacy Responsible for inspection?
- What is the definition of public place?
- Who determines who the authorized entities are?

A motion was made by Ms. Martini and seconded by Mr. Sellers requesting that Mr. Dryden draft a letter of Board concerns. The Board members appreciate the intent of the bill however they are opposed to SB162 due to the many public safety issues listed above.

Continuing Education – Joli Martini, Bonnie Wallner, Tejal Patel and David Dryden:

No Report

Consumer Affairs – Ken Sellers, Jay Galloway and Julia Wheatley

No Report

Professional Liaisons – Kim Robbins and Tejal Patel:

No Report

Controlled Substance Liaisons – Kenneth Sellers, Tejal Patel, Jay Galloway and David Dryden:

No Report

Patient Safety Committee – Michelle McCreary (Chair), Kenneth Sellers, Tejal Patel, Kimberly Robbins, Susan Esposito, Joli Martini, Hooshang Shanehsaz, Jay Patel

Ms. Esposito publicly thanked Ms. McCreary for chairing the committee. Ms. Esposito expressed the committee had completed its role at this time. No further meetings will be scheduled at this time and requested the committee be removed from the agenda.

COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS

Collaborative Care Committee – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

Ms. Esposito requested this item be reported under the legislative committee and this heading be removed from the future agenda.

BOARD CORRESPONDENCE

None

EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim

Mr. Dryden reported that he had recently attended the NASCSA meeting and he and Ms. Esposito attended the FDA 50 state meeting in Washington DC.

Mr. Dryden reviewed the new distributor tracking issues that were addressed at the NASCSA meeting. Distributed drugs will be tracked by individual bottles through the distribution process.

University of Delaware personnel and Mr. Dryden met law enforcement (Delaware State Police, New Castle County Police and DEA) to introduce the initial PMP efforts of geo-mapping. This project will utilize demographics, social values and law enforcement data to better understand drug issues.

Ms. McCreary reported that she has completed the following inspections:

- 1 – Methadone Clinic New Opening Inspection
- 1 – Preconstruction Inspection
- 1 – Clinic/Hospital New Opening Inspection
- 3 – Change of Ownership Inspections

- 4 – Follow up Inspections
- 1 – Clinic/Surgery Center Inspection
- 3 – Routine Inspections

NEWSLETTER UPDATES

No Report

OTHER BUSINESS BEFORE THE BOARD

Ms. Mast reported that 2016 will bring the use of iPads during the board meetings. This will reduce the significant amount of paper resources currently required for the meeting.

PUBLIC COMMENT

NEXT SCHEDULED MEETING

The next meeting is scheduled for January 20, 2016 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the Board a motion to adjourn the meeting was made by Mr. Shanehsaz, and seconded by Ms. Patel at 12:11 pm. The motion unanimously carried.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast", written in a cursive style.

Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy